K00 3575

JAN 1 7 2001

GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 414-544-3894, November 15, 2000

- Identification of the Product
  3.0T Signa VH/*i* Magnetic Resonance System

  Manufactured by: GE Medical Systems
  3200 N. Grandview Blvd.
  Waukesha, WI 53188

- Marketed Devices

  The 3.0T Signa VH/*i* Magnetic Resonance System with SW version VH2, is substantially equivalent to the currently marketed 3.0T Signa VH/*i* Magnetic Resonance System.

- Device Description

  The 3.0T Signa VH/*i* Magnetic Resonance System with SW version VH2, utilizes a superconducting magnet to acquire 2D single slice and multi-slice, and 3D volume images. The GE 3.0T Signa VH/i MR System is a high resolution, head imaging system operating at 3 Tesla. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences. Images are acquired and reconstructed using 2D and 3D Fourier transformation techniques. With proton spectroscopy option both single voxel spectra and spectroscopic images are acquired and reconstructed. The system uses optimized software, real-time image processing, and a spiral acquisition to provide functionality for neurology applications. The system is intended for high-resolution anatomical applications and shorter scan times.

- Indications for Use

  The 3.0T Signa VH/i system is a head-only scanner designed to support higher resolution imaging and shorter scan times. The 3.0T Signa VH/i system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head. The images produced by the 3.0T Signa VH/i system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. Use of enhanced applications enables production of high quality neurological images in advanced brain studies. The Signa system allows also single voxel spectroscopy and spectroscopic imaging acquisition. When interpreted by a trained physician, these images and spectra provide information that can be useful in determining a diagnosis.

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SUMMARY OF SAFETY AND EFFECTIVENESS

- Comparison with Predicate

  The 3.0T Signa VH/*i* Magnetic Resonance System with SW version VH2 is similar to the currently marketed 3.0T Signa VH/*i* Magnetic Resonance System with the primary differences being the addition of spectroscopy which is similar to the currently marketed GE Probe Option and optimized software for neurology applications which is similar to applications provided with the currently marketed Signa CV/i System.

- Summary of Studies

  The 3.0T Signa VH/*i* Magnetic Resonance System was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International medical equipment safety standard and IEC 601-2-33, Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. The 3T Signa VH/*i* Magnetic Resonance System is comparable to the 3.0T Signa VH/*i* Magnetic Resonance System and the Signa CV/i Magnetic Resonance Systems.

- Conclusions

  It is the opinion of GE that the 3.0T Signa VH/*i* Magnetic Resonance System with SW version VH2 is substantially equivalent to the currently marketed 3.0T Signa VH/*i* with the addition of applications currently on the Signa CV/i Magnetic Resonance System, and the GE Probe Option. The 3.0T Signa VH/*i* Magnetic Resonance System with SW version VH2 does not include any new indications for use, nor does use of this device result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2001

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems, Inc.
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K003575
3.0T Signa VH/i Magnetic Resonance System
Dated: November 15, 2000
Received: November 20, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNI

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003575

Device Name: 3.0T Signa VH/*i* Magnetic Resonance System

Indications for Use:

The 3.0T Signa VH/*i* system is a head-only scanner designed to support higher resolution imaging and shorter scan times. The 3.0T Signa VH/*i* system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head. The images produced by the 3.0T Signa VH/*i* system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. Use of enhanced applications enables production of high quality neurological images in advanced brain studies. The Signa system allows also single voxel spectroscopy and spectroscopic imaging acquisition. When interpreted by a trained physician, these images and spectra provide information that can be useful in determining a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER ~~PAGE IF NEEDED~~)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Legeman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003575

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)